IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., and NORTON (WATERFORD) LTD.,	:	Consolidated Civil Action No. 20-10172 (JXN)(MAH)
Plaintiffs,	:	CONFIDENTIAL – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER
v.	:	
CIPLA LTD., AUROBINDO PHARMA LLC, AUROBINDO PHARMA USA, INC., and AUROLIFE PHARMA LLC,	:	
Defendants.	:	

REPLY EXPERT REPORT OF DR. REYNOLD A. PANETTIERI, JR., M.D.

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I. Introduction, Qualifications, Compensation, and Prior Testimony

1. My name is Reynold Panettieri, Jr., and I am the Director of the Institute for Translational Medicine and Science and Vice Chancellor for Translational Medicine and Science at Rutgers University. I have been a Professor of Medicine at Rutgers's Robert Wood Johnson Medical School ("Rutgers Medical School") since 2015.

2. In addition to my teaching responsibilities, I am an attending physician at Rutgers Medical School in the areas of pulmonary and critical care medicine. I have more than 30 years of experience in the management of asthma patients. Over the past 30 years, I have treated over a thousand patients with asthma or chronic obstructive pulmonary disease ("COPD").

3. I also have extensive research experience as a respiratory pharmacologist and toxicologist. My research experience provides a unique perspective and expertise in the use of corticosteroids (e.g., beclomethasone dipropionate) and bronchodilators (e.g., albuterol sulfate) as therapies for treating patients with asthma and COPD.

4. I received a B.S. in Biology from St. Joseph's University in 1979, and I received an M.D. from the University of Pennsylvania in 1983.

5. I completed my internship in Internal Medicine at the Hospital of the University of Pennsylvania in 1989. I then completed my residency in Internal Medicine at the Hospital of the University of Pennsylvania later that year. I further completed a research fellowship in Pulmonary Diseases at the Hospital of the University of Pennsylvania in 1986.

6. I began teaching at the University of Pennsylvania Department of Medicine as an Assistant Professor in 1990, and I was named the Robert L. Mayock & David A. Cooper Professor in 2001. I continued in that role until 2015, when I became an Emeritus Professor. While at the University of Pennsylvania, I served as the Director of the Airways Biology Initiative from 2003 to 2015 and Director of the pulmonary function laboratory. These laboratories conducted studies that

measured the pulmonary function of patients with asthma and COPD. I also served as the Deputy Director for the Center for Excellence in Environmental Toxicology (CEET) from 2009 to 2015, and as Director for the Integrated Health Science Facility Core (the "Core") from 2007 to 2015. The Core conducted human toxicology and pharmacological studies in environmental health that included asthma and COPD. Over the last 30 years, I have conducted translational research in how short acting bronchodilators such as ProAir® and beclomethasone (Qvar®) additively alter airway smooth muscle function to improve bronchodilation in asthma and COPD.

7. I have provided in this matter an Opening Expert Report with respect to each Defendant Group in this case, namely (1) Cipla Ltd. ("Cipla") and (2) Aurobindo Pharma, LLC, Aurobindo Pharma USA, Inc., and Aurolife Pharma LLC (collectively, "Aurobindo"), both of which are dated April 29, 2022. In those reports, I addressed various objective indicia of non-obviousness. I refer collectively to both of my Opening Reports in this matter as my "Opening Report." I maintain the opinions I offered in my Opening Report and I incorporate them fully as though set forth herein. In this report, I respond to Mr. Gregor Anderson's opinions as provided in his reports dated April 29, 2022 and June 14, 2022.

8. In forming my opinions, I have considered materials cited in this report. I have also considered my Opening Report (and the materials cited in it); the sections of the reports of Mr. Anderson cited in the previous paragraph addressing objective indicia of non-obviousness (and the materials cited in them); and my education, training, and experience. In addition to the opinions and bases set forth in this report, my testimony may include responses to facts, arguments, allegations, or references raised by Defendants or their experts in this litigation. I reserve the right to supplement my opinions if additional information is provided to me or if additional research leads me to conclude that supplementation is necessary.

9. I set forth my qualifications, compensation, and prior testimony in my Opening Report. My qualifications, compensation, and prior testimony have not changed since that time.

II. Asserted Patents

10. As stated in my Opening Report, I have been informed that Teva has asserted the following patents and claims against Defendants Cipla and Aurobindo:

a. U.S. Patent No. 9,463,289 (the "'289 Patent"), Claims 1-8;

b. U.S. Patent No. 9,808,587 (the "'587 Patent"), Claims 1-8, 11-22;

c. U.S. Patent No. 10,086,156 (the "'156 Patent"), Claims 1, 9, 11-13; and

d. U.S. Patent No. 10,561,808 (the "'808 Patent"), Claims 1, 27-28

(collectively, the "Asserted Patents" and "Asserted Claims").

11. I have been informed that Mr. Anderson has stated that earliest possible priority date for the Asserted Claims is May 18, 2010, and the earliest possible "critical date" is May 18, 2009. I have been informed that Dr. Lewis has offered the opinion that the Asserted Claims are entitled to a priority date of November 5, 2009; alternatively, December 2, 2009; alternatively, March 16, 2010; alternatively May 18, 2010; alternatively November 29, 2010; and alternatively May 18, 2011. I have not been asked to provide an opinion as to whether any of these dates is correct, and I express no opinion on that issue.

12. I have applied these dates in my analysis. For purposes of my opinions, it does not matter which date between May 18, 2009, and May 18, 2011, is the ultimate priority date. My opinions would remain the same based on any priority date within that range. Accordingly, I refer to the "priority date" in the singular throughout this report.

13. Each of the Asserted Patents names the following individuals as inventors: Declan Walsh, Derek Fenlon, Simon Kaar, Jan Geert Hazenberg, Daniel Buck, Paul Clancy, Robert Charles Uschold, and Jeffrey A. Karg.

III. Legal Standards

14. I have been asked to apply certain legal principles in forming my opinions. Below, I summarize some of the principles that I have applied in performing my analysis.

A. The Person of Ordinary Skill in the Art

15. As explained in my Opening Report, I have been asked to assume that the person of ordinary skill in the art ("POSA") for the Asserted Claims, as of the Asserted Patents' priority date, would have had the skills, education, and expertise of a team of individuals working together to research, develop, and manufacture an inhalation aerosol product with a dose counter. Such a team would have included individuals with master's degrees in mechanical engineering, design engineering, or related fields, with at least two years of post-graduate experience in developing inhalation aerosol products, or bachelor's degrees in similar fields of study, with a commensurate increase in their years of postgraduate experience. Such a team also would have been familiar with a variety of issues relevant to researching, developing, and manufacturing inhalation aerosol products with dose counters. In my opinion, the team also would have had access to an individual with a medical degree and experience in treating patients with inhalation aerosol devices.

16. For purposes of my opinion in this report, I have formed my opinions from the perspective of an individual with a medical degree and experience in treating patients with inhalation aerosol devices.

17. In his Rebuttal Report, Mr. Anderson offers the following definition of the POSA for the Asserted Patents:

> A person of ordinary skill in the art pertaining to the subject matter of Patents-in-Suit, as of the earliest possible effective U.S. filing date of May 18, 2010, would have been a person with a bachelor's degree in pharmaceutical science or a related discipline, and at least 2-3 years of product development experience with design and

> manufacture of metered dose inhalers. Alternatively, a person of ordinary skill in the art would have a master's degree or Ph.D. in pharmaceutical science, mechanical or medical device engineering, or a related discipline, and at least 1-2 years of product development experience with metered dose inhalers and counter systems. A POSA may have also worked as part of a multi-disciplinary team of scientists in pursuit of developing a pharmaceutical product and drawn upon not only his or her own skills, but also consulted with others of the team having specialized skills.

Anderson Rebuttal Rep. on Secondary Considerations ¶ 18 (incorporating Anderson Opening Rep. ¶ 58).

18. In addition, Mr. Anderson states that he "disagree[s]" with the "requirement that a POSA include a physician." Anderson Rebuttal Rep. on Secondary Considerations ¶ 20. Mr. Anderson states the following:

> Dr. Panettieri does not explain the role of a physician in designing an inhaler. In my experience designing inhalers, a physician might help identify the need for an inhaler and the condition it would treat, but a physician would not design the final product, i.e., the inhaler. In my experience, the final would be designed by an engineer or scientist. At most, the physician will then verify and validate the needs that the physician identified.
>
> It is my opinion that I satisfy both the definition of a POSA set forth by myself and by Dr. Panettieri. However, given Dr. Panettieri's apparent lack of experience developing dose counters, it is my opinion that he does not satisfy either definition of POSA.

Anderson Rebuttal Rep. on Secondary Considerations ¶¶ 20-21.

19. It is unclear to me how Mr. Anderson derived that definition of the POSA, and I disagree with it to the extent that it excludes physicians such as myself. As I stated in my Opening Report and above, the POSA would have had the skills, education, and expertise of a team of individuals working together to research, develop, and manufacture an inhalation aerosol product with a dose counter. Such a team would have had access to, among other things, an individual with a medical degree and experience in treating patients with inhalation aerosol

devices. Whether the physician designs "the final product, i.e., inhaler," as Mr. Anderson opines, is irrelevant. The team would take into account the perspective of an individual (such as myself) with a medical degree and experience in treating patients with inhalation aerosol devices when designing the inhalation device. The ultimate value of the device requires adept use by the patient that improves clinical outcomes. Indeed, even Mr. Anderson agrees that a physician would be involved in verifying and validating needs.

20. As a physician, I am able to observe first-hand and appreciate the needs of the physicians who ultimately prescribe those devices and the patients who use them. As a result, pharmaceutical companies, including AstraZeneca, Glaxo-Smith Kline, Boehring-Ingelheim, Novartis, Genentech, Sanofi, and Regeneron frequently seek my advice for purposes of designing and improving inhalation therapeutic devices. Because of this knowledge and experience, I am frequently able to provide them with information about physician and patient needs that would not otherwise be available to them. For example, the companies for whom I consult are frequently surprised to learn that human factors, such as aesthetics and ergonomics, are among the most important elements of inhalation aerosol device design because they affect, and in some cases dictate, whether patients actually comply with their prescriptions. Focusing exclusively on the engineering aspects of designing and improving inhalation aerosol devices misses out on these and other important factors. In addition, Sanofi, Regeneron, and Genentech have requested my expertise in devising inhalers to deliver biologic medications.

21. It is my opinion that Mr. Anderson's opinions do not properly take into account the perspective of a person with a medical degree or experience in treating patients with inhalation aerosol devices, as he does not have that experience and did not consult an individual with that experience. Indeed, as I explain throughout this report, Mr. Anderson's criticisms of

my opinions demonstrate his lack of knowledge of, and experience in, these matters. Mr. Anderson lacks the expertise in determining the efficacy of inhalation devices regarding their use to improve patient care.

B. Obviousness

22. As explained in my Opening Report, I have been informed that Defendants contend that the inventions of the Asserted Claims would have been obvious to the POSA as of their priority date. I have been informed that analysis of whether a claim would have been obvious depends on (a) the scope and content of the prior art, (b) the differences between the claimed invention and the prior art, (c) the level of ordinary skill in the art, and (d) any secondary considerations of non-obviousness. I have been informed that the use of hindsight must be avoided because the obviousness of an invention is evaluated from the perspective of the POSA at the time the invention was made. Thus, in conducting an obviousness inquiry, one must be aware of the distortion caused by hindsight bias and must be cautious to avoid reading into the prior art the teachings of the claimed invention at issue.

23. I have been informed that a proper obviousness analysis involves an evaluation of any secondary considerations of non-obviousness, also referred to as "objective indicia of non-obviousness." I have been informed that commonly recognized objective indicia include, among other things, evidence of long felt but unsolved needs, failure of others, industry acceptance, and praise. I have been informed that the consideration of such objective indicia guards against hindsight bias and that, in appropriate circumstances, evidence of objective indicia may be determinative of the ultimate question of obviousness. I have been informed that, in order to affect the obviousness analysis, any objective indicia must have a sufficient nexus to the claimed invention(s).

IV. Claim Construction

24. I have been informed that claim construction refers to the process in which the Court determines the legal meaning of a patent's claims. I have been informed that a patent's claims should be construed according to their ordinary and customary meaning in view of the patent's specification and prosecution history, unless the patent defines a claim term, in which case that definition should be applied.

25. As explained in my Opening Report, I have been informed that the parties have agreed to the following claim constructions. I have applied those constructions in forming my opinions.

No.	Term	Agreed-Upon Construction
1	"canister housing" '289 patent, claim 1 '587 patent, claims 1, 12, and 13	"the portion of the inhaler body that is arranged to retain a medicament canister"
2	"inside surface" '289 patent, claim 4 '587 patent, claims 4 and 17	"an interior surface"
3	"body" '156 patent, claim 1	"the body of the inhaler"
4	"associated with" '156 patent, claim 1	"related to"
5	"canister support formation" '289 Patent, claims 1, 4 '587 Patent, claims 1, 4, 11-13, 15	"a formation arranged to reduce canister rocking"
6	"actuator"	"A structure within the dose counter that can be moved by the canister, is moveable relative to

	’156 Patent, claims 1, 2, 12	other components of the dose counter, and effectuates movement of at least one additional dose counter component.”
7	“actuator pawl arranged to engage with a first tooth of the ratchet wheel” ’156 Patent, claim 1	“a pawl that is a part of the actuator of the dose counter that is arranged to engage with a tooth of the ratchet wheel.”
8	“wall surfaces separating the canister receiving portion and the counter chamber” ’156 Patent, claim 1	“wall surfaces of the inhaler body which are substantially perpendicular to the direction of canister movement and which divide the canister-receiving portion and counter chamber”
9	“regulator” ’808 Patent, claims 1, 27	“a structure of the dose counter that modulates motion of the counter display”
10	“regulate motion of the counter display” ’808 Patent, claim 1	“modulate motion of the counter display”
11	“ratchet wheel” ’156 Patent, claims 1, 9, 12	“a wheel having a plurality of circumferentially spaced teeth arranged to engage with a pawl”
12	“first direction” ’808 Patent: 1	“single direction at a time”
13	“main surface of the inner wall” ’289 Patent, claim 1 ’587 Patent, claim 1, 12, 13	“inside surface of the vertical cylindrical portion of the inhaler body, where vertical means substantially parallel to the primary direction of the movement of the medicament canister when it is pressed downward by the user to expel medicament”
14	“inner wall through which a portion of the actuation member extends” ’289 Patent, claim 3	“an internal wall of the inhaler body that is horizontal, through which a portion of the actuation member extends, where horizontal means substantially perpendicular to the primary direction of the movement of the medicament canister when it is pressed downward by the user

	'587 Patent, claims 3, 13	to expel medicament"
15	"inner wall" '289 Patent, claims 1, 4 '587 Patent, claims 1, 4, 12, 13, 15, 21, 22	"an internal wall of the inhaler body, which includes a main surface of the inner wall and the inner wall through which a portion of the actuation member extends, but excludes the bottom surface, or floor, of the inhaler body"
16	"protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler" '587 patent, claim 1	"guards against unwanted actuation by reducing rocking of the medicament canister relative to the main body of the inhaler that would otherwise be of a magnitude sufficient to move the dose counter's actuator enough to cause unwanted incrementing (or decrementing) of the dose counter"

See Joint Claim Construction Chart 3-5.

26. As explained in my Opening Report, I have been informed that the parties dispute the meaning of the following claim terms and have proposed competing constructions. I have been informed that the Court has yet to rule on these disputes. Accordingly, I have applied both parties' constructions in forming my opinions. In my opinion, and as explained in this report, Defendants both infringe each of the Asserted Claims under either side's proposed constructions.

No.	**Term**	**Plaintiffs' Construction**	**Defendants' Construction**
1	"actuation member" '289 Patent, claims 1, 3 '587 Patent, claims 1, 3, 11, 12, 13 '156 patent, claims 12	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a component of the dose counter's actuator that transmits motion from the canister to the actuator"	"pin arranged to engage with a medicament canister and effect movement causing the dose counter to record a count"
2	"[lying or lie] in a common plane coincident with the longitudinal axis X"	Plain and ordinary meaning in view of the claims, specification, and prosecution history.	"aligned in a single plane such that a straight line can be drawn though the center of the central outlet port, a canister support formation

No.	Term	Plaintiffs' Construction	Defendants' Construction
	'289 Patent, claim 1 '587 Patent, claims 1, 12, 21, 22	Features lie on a common plane coincident with the longitudinal axis X if it is possible to draw a straight line connecting those features that passes through the center of the stem block.	located directly adjacent to the actuation member, and the actuation member"
3	"positioned at opposite ends of the inside surface of the main body to face each other" '289 Patent, claim 7 '587 Patent, claims 7, 18	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "located on opposite sides from one another on the inside surface of the main body, and extending outwardly from the inner wall towards each other"	"positioned directly across from one another such that a straight line can be drawn from one support rail through the center of the longitudinal axis X to the facing support rail"
4	"step[(s)] formed thereon" '289 Patent, claims 5, 8 '587 Patent, claims: 5, 8, 16, 19	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a location of changing width dimension thereon"	"A stepwise increase in the extent to which the support rail extends inwardly"
5	"first reset position" '156 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a position of the actuator in which the actuator pawl is brought into engagement with the first tooth of the ratchet wheel and which is before the canister fire configuration"	"configuration in which the actuator pawl is above the datum plane, but closer to the datum plane than in the start configuration, and is just engaged with one of a tooth of the ratchet wheel"
6	"canister fire sequence" '156 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and	"process of ejecting medicament from an inhaler where the actuator

No.	Term	Plaintiffs' Construction	Defendants' Construction
		prosecution history. "a sequence of configurations and positions that occur before, while, and after the medicament canister fires medicament"	pawl follows a particular sequence of movement from the start configuration to the reset configuration, to the [fire configuration as, to the count configuration, before returning to the start configuration upon release of pressure on the canister, where in the start configuration, prior to depression of the canister, the count pawl is engaged with a tooth of the ratchet wheel and the actuator pawl is spaced from the ratchet wheel."
7	"canister fire configuration" '156 Patent, claims 1, 2	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a configuration of the dose counter in which the medicament canister fires medicament"	"configuration in which the actuator pawl is lower than in the first reset position and below the datum plane and the medicament is ejected"
8	"count configuration" '156 Patent, claims 1, 2	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a configuration of the dose counter whereby the dosage indicator has indicated a count"	"configuration in which the actuator pawl is further below the datum plane than when in the canister fire position and the dose counter has counted one dose"
9	"datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister"	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a plane that passes	"plane or line passing through the bottom surface of a structure into which the valve stem of a medicament canister is inserted, wherein the

No.	Term	Plaintiffs' Construction	Defendants' Construction
	'156 Patent, claim 1	through a shoulder of the portion of the inhaler body that engages the valve stem and is perpendicular to the direction of movement of the medicament canister"	bottom surface is where the valve stem block meets a passageway to a nozzle for directing the canister contents towards an air outlet"
10	"the body" '156 Patent, claim 12	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "inhaler body" - '156 Patent, 22:64, 67 "dose counter body" - '156 Patent, 22:66	This term is indefinite.
11	"counter display arranged to indicate dosage information" '808 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a component of the dose counter that displays information regarding the number of doses remaining"	"structure displaying the number of doses remaining"
12	"first station" '808 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a first region"	"first structure on which the counter is located"
13	"second station" '808 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a second region"	"second structure, separate from the first structure, to which the counter display is moved"
14	"aperture"	Plain and ordinary meaning in view of the claims, specification, and	"hole"

No.	Term	Plaintiffs' Construction	Defendants' Construction
	'289 Patent, claim 3 '587 Patent, claims 3, 13, 20-22	prosecution history. "an opening or open space: hole"	
15	"separate counter chamber" '156 Patent, claim 12	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a separate chamber of the inhaler in which the dose counter is located"	"discrete space or cavity defined by the main surface of the inner walls and the inner wall through which a portion of the actuation member extends in which the dose counter is located"
16	"count pawl" '156 Patent, claims 1, 9	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a pawl that is a component of the dose counter that is capable of engaging with a second tooth of the rachet wheel"	"a pawl that is part of the dose counter, separate from an actuator pawl, that is arranged to engage with a second tooth different from the first tooth of the ratchet wheel"

See Joint Claim Construction Chart 6-10.

27. I reserve the right to supplement my opinions in the event that the Court construes these terms or the parties present additional arguments or evidence relevant to these issues.

V. Summary of Opinions

28. The following paragraphs summarize some of my opinions in this matter at a high level. This summary is not meant to limit the opinions expressed below in greater detail, but instead to provide a general overview of the subject matter of my testimony.

29. I have been asked to respond to the Opening Report of Mr. Anderson, dated April 29, 2022, and the Rebuttal Report of Mr. Anderson, dated June 14, 2022, in which he opines that the inventions claimed by the Asserted Claims lack certain objective indicia of non-obviousness.

30. I disagree with Mr. Anderson's opinions that the inventions recited in the Asserted Claims failed to satisfy long-felt, unmet needs in the field of pulmonary medicine (or, in Mr. Anderson's terms, "inhalers").

31. I disagree with Mr. Anderson's opinions that prior art devices or disclosures had already satisfied these long-felt, unmet needs that existed as of the priority date of the Asserted Patents.

32. I disagree with Mr. Anderson's opinions that others tried and succeeded in developing solutions to solving these long-felt, unmet needs that existed as of the priority date of the Asserted Patents.

33. I disagree with Mr. Anderson's opinions that there was no industry acceptance or praise for the inventions in the Asserted Patents.

34. I disagree with Mr. Anderson's opinions that Defendants did not copy the claimed inventions.

35. Below, I respond to Mr. Anderson's analysis. I have only responded to the arguments Mr. Anderson makes with respect to objective indicia of non-obviousness in his Opening and Rebuttal Reports. Should Mr. Anderson be permitted to expand or further supplement his analysis, I reserve the right to offer additional opinions that address any new assertions.

VI. Argument

A. The Asserted Patents Satisfied Multiple Long Felt, Unmet Needs

36. Mr. Anderson opines that the claimed inventions did not satisfy "'multiple long felt-needs in the field of pulmonary medicine' including 'needs for inhalers with those dose counters that had sufficient functionality, accuracy …, reliability, maintainability (and ability to be cleaned), robustness, manufacturability, minimal impact on device performance, and human

factors (including aesthetics, ergonomics, and other human factors).'" Anderson Rebuttal Rep. on Secondary Considerations ¶ 24. Mr. Anderson asserts that certain prior-art devices satisfied these multiple, long-felt needs; that the needs identified in the references that I relied on in my Opening Report had been met as of the priority date; and that Qvar® HFA with dose counter and ProAir® HFA with dose counter did not satisfy these multiple, long-felt needs. *See* Anderson Rebuttal Rep. on Secondary Considerations § XI. For the reasons set out below and in my Opening Report, *see* Panettieri Opening Rep. § VI (¶¶ 83-96), Mr. Anderson is incorrect.

1. Prior-Art Devices Failed to Satisfy Multiple, Long-Felt Unmet Needs

37. Mr. Anderson states that "most" of the long-felt needs that I identified in my Opening Report merely "relate to the desire for a dose counter on an inhaler generally." Anderson Rebuttal Rep. on Secondary Considerations ¶ 25. According to Mr. Anderson, "[d]ose counters, and dose counters on inhalers were well-known and commercially available by 2009," and these devices satisfied the needs that I identified. Anderson Rebuttal Rep. on Secondary Considerations ¶ 25.

38. I disagree with Mr. Anderson. As I explain in my Opening Report and below, the needs satisfied by the Asserted Patents do not "relate to the desire for a dose counter on an inhaler generally." Instead, they satisfied multiple, *specific*, long-felt needs in the field of pulmonary medicine, including the needs for inhalers with dose counters that had sufficient functionality, accuracy (including with respect to under- and over-counting), reliability, maintainability (and ability to be cleaned), robustness, manufacturability, minimal impact on device performance, and human factors (including aesthetics, ergonomics, and other human factors). *See* Panettieri Opening Rep. § VI (¶¶ 83-96).

39. Additionally, as I explain my Opening Report and below, the dose counters that were commercially available as of the priority date, including the dose counters purportedly

disclosed by the '406 Publication or included in Ventolin® HFA, Flovent® HFA, Advair® Diskus, and Serevent® Diskus, failed to satisfy the need for devices with the properties of the claimed inventions. *See* Panettieri Opening Rep. § VI.A.2 (¶¶ 64-74). That is, these counters failed to satisfy the specific, long-felt needs satisfied by the claimed inventions, including combination of those needs satisfied by those inventions.

a. The '406 Publication

40. Mr. Anderson asserts that the '406 Publication, "developed years before the asserted patents," discloses an inhaler with a dose counter which "satisfied any need for an inhaler with a dose counter having sufficient functionality, accuracy, reliability, maintainability, robustness, manufacturability, minimal impact on device performance and human factors." Anderson Rebuttal Rep. on Secondary Considerations ¶¶ 26-28; Anderson Opening Rep. ¶¶ 472-73 (similar). For the reasons set forth below, I disagree with Mr. Anderson.

41. To begin with, Mr. Anderson opines that the '406 Publication "discloses the dose counter used in the Cipla and Aurobindo inhalers," and the "dose counter used in Dulera®." Anderson Rebuttal Rep. on Secondary Considerations ¶ 26. I have been informed that Dr. Lewis has offered the opinion that the dose counter disclosed in the '406 Publication dose not disclose the dose counter (and inhaler/dose counter combination) used in Cipla's and Aurobindo's ANDA Products, in particular because the '406 Publication fails to disclose, or otherwise render obvious, the inventions of the asserted claims. *See* Lewis Rebuttal Rep. §§ IV.A, VI. I have not independently assessed whether the '406 Publication discloses the dose counter used in Cipla's and Aurobindo's ANDA Products. Nevertheless, Dr. Lewis's opinion accords with my own experience. The needs I identify in my reports continued to persist after the '406 Publication's November 1, 2007 publication date

42. Additionally, I disagree with Mr. Anderson's opinion that the '406 Publication's disclosures satisfied the needs for an inhaler with a dose counter "sufficient functionality, accuracy, reliability, maintainability, robustness, manufacturability, minimal impact on device performance and human factors." On those points, Mr. Anderson fails to provide any evidence from the perspective of a treating physician in pulmonary medicine, and his opinion conflicts with my knowledge of and experience with the specific needs faced by individuals in that field. Indeed, the '406 Publication itself provides no evidence that any of its disclosures satisfy any of these needs, much less all of them, despite acknowledging that robustness, reliability, manufacturability, accuracy, precision, and unwanted actuation are important characteristics for a dose counter. *See, e.g.*, '406 Publication, ¶ [0006].

43. Mr. Anderson asserts that FDA's approval of the 3M dose counter, which he alleges incorporates the dose counter disclosed by the '406 Publication, demonstrates that the "dose counter is safe and effective." Anderson Rebuttal Rep. on Secondary Considerations ¶ 28. Mr. Anderson also states that: (1) the dose counter disclosed in the '406 Publication has a "lifespan" that crosses "multiple products"; (2) "Defendants' testing also demonstrates that the . . . dose counter [disclosed by the '406 Publication] is safe, effective, reliable, and meets patient needs"; and (3) the dose counter "addressed any needs identified by FDA's industry guidance." Anderson Rebuttal Rep. on Secondary Considerations ¶ 28.

44. I disagree with Mr. Anderson's assertions. Mr. Anderson fails to demonstrate that the '406 Publication actually discloses a dose counter that is used in the products he identifies (e.g., Dulera®). And even assuming that Mr. Anderson's assertion is correct, the fact that the dose counter disclosed by the '406 Publication is a counting mechanism that has been used by multiple products and received FDA approval does not mean that the device has the claimed

properties—that is, superior functionality, accuracy (including, with respect to over- and under-counting), reliability, maintainability (and ability to be cleaned), robustness, manufacturability, minimal impact on device performance, and human factors—of the inventions recited Asserted Claims.

45. To the contrary, based on my experience with each of these devices, none of them satisfies the needs, and combinations of needs, satisfied by the claimed inventions. Indeed, I have received far fewer complaints from patients about Qvar® HFA and ProAir® HFA with respect to these factors than the devices Mr. Anderson cites.

b. Other Dose Counters

46. Mr. Anderson opines that by 2009, there were "numerous inhalers" with dose counters, including, "the Ventolin HFA, Flovent HFA, Advair Diskus, and Serevent Diskus." Anderson Rebuttal Rep. on Secondary Considerations ¶ 29; *see also* Anderson Opening Rep. ¶¶472-73 ("[N]umerous dose counters were marketed prior to May 2009."). According to Mr. Anderson, "These inhalers all had dose counters that provided the functionality, accuracy, reliability, maintainability, robustness, manufacturability, minimal impact on device performance and human factors." Anderson Rebuttal Rep. on Secondary Considerations ¶ 29. I disagree with Mr. Anderson.

47. As an initial matter, Mr. Anderson's opinions demonstrate his lack of knowledge of and experience with the needs of physicians and patients who use the inhalers and dose counters that he describes in his reports. For example, throughout his opinions, Mr. Anderson assumes perfect patient use of these devices. In my experience as a physician, I am required to account for practical realities, which often involve imperfect patient use. What is remarkable about the inventions recited in the Asserted Claims is that they satisfy the above-mentioned needs, while also accounting for these realities.

48. Mr. Anderson's mistaken opinions about the specific devices he identifies exemplify his lack of relevant knowledge and expertise. As I discuss in my Opening Report, the Ventolin® HFA and Flovent® HFA include counting mechanisms that are fixed near the valve of the canister. *See* Panettieri Opening Rep. ¶ 73. In my experience as a prescribing physician, this type of counting mechanism increases the bulkiness of the device near the "boot" of the inhaler and affects usability and, potentially, efficacy. *See* Panettieri Opening Rep. § VI.A.2 (¶ 73) (citing '021 Publication, ¶ [0006]). Because of the location of the dose counter, patients have a lower margin of error when pressing down on the canister. In addition, the added bulkiness increases the difficulty for a patient to actuate the device, especially for arthritic patients, children, or other persons with small hands. *See* Panettieri Opening Rep § VI.A.2 (¶ 73). Patients are less likely to adhere to the medication regimen if the dose counter in their inhaler reduces the aesthetic and/or ergonomic value of the device or otherwise makes it less convenient to carry and use.

49. The Advair® Diskus and Serevent® Diskus inhalers present similar problems. In my experience as a treating physician, these devices are bulky, and patients, especially arthritic patients, children, or other persons with small hands, have difficulty actuating the device. As I discuss above, patients are less likely to adhere to the medication regiment if the dose counter in their inhaler reduces the aesthetic and/or ergonomic value of the device or otherwise makes it less convenient to carry and use. Moreover, the Advair® Diskus and Severent® Diskus inhalers, which are dry powder inhalers, require users to take multiple, manual steps in order to use the devices appropriately. For example, the user has to open the Diskus; the user has to hold the Diskus in a level, flat position with the mouth piece towards the user, and then slide the lever away from the mouthpiece as far as it will go until it clicks; the user has to exhale as long as the

user can while holding the Diskus level and away from his or her mouth, and then breathe in quickly and deeply through the Diskus; the user then has to breathe out and close the Diskus; finally, the user has to rinse out his or her mouth with water after breathing in the medicine. The dose counters in those devices are configured accordingly. In my experience as a treating physician in the field of pulmonary medicine, patients are less likely to properly use their inhalation devices when they are required to take these many steps. When patients are less likely to properly use their devices, they increase the possibility that they will not receive the adequate amount of inhalation medication.

50. Mr. Anderson also opines that "human factors" such as "aesthetics or ergonomic value" are "not claimed (or meaningfully described) in any of the asserted patents." Anderson Rebuttal Rep. on Secondary Considerations ¶ 30; *see* Anderson Opening Rep. ¶ 477. I disagree. To begin with, I have been informed that nexus does not require that a claim expressly recite the advantages of a patented invention. As Dr. Lewis explains in his Reply Report, the combination of elements recited in the claims sets forth an inhalation device with an internal, precise, and accurate does counter that is situated in a counter chamber. *See* Lewis Reply Rep. § VI.A.1.a.2. In offering this opinion, Mr. Anderson appears to focus narrowly on the fact that the Asserted Patents do not use the term "human factors" or similar phrases. What is important, however, is that the inventions recited in the Asserted Claims provide the unique combination of elements from which these advantages flow. Unsurprisingly, the Asserted Claims do not refer to those terms expressly because they describe the inventions in terms of their design. In my opinion, however, it is those designs that solved the needs I describe. Further, Mr. Anderson's comments clearly demonstrate his unfamiliarity of inhaler use in patients.

51. Mr. Anderson further opines that "each of these devices falls within the scope of the FDA's 2003 guidance on which [I] rel[y] as identifying the purported needs." Anderson Rebuttal Rep. on Secondary Considerations ¶ 30. He also states that: (1) Ventolin® HFA, Flovent® HFA, Advair® Diskus, and Serevent® Diskus were all approved by the FDA "with a dose counter" before the priority date; (2) "FDA's approval of these devices demonstrates that the dose counters they use are safe, accurate, and reliable"; and (3) "any need for such inhalers by 2009 had been met." Anderson Rebuttal Rep. on Secondary Considerations ¶ 30. I disagree.

52. Mr. Anderson appears to assume that FDA's guidances, such as the 2003 FDA Guidance, conclusively establish the sum total of the needs in the field. Once again, Mr. Anderson's opinions demonstrate his lack of knowledge of or experience with medical needs. Although FDA's guidances often establish the minimum requirements, physicians and patients often face additional needs not expressly addressed by those guidances.

53. In this case, contrary to Mr. Anderson's assertion, the fact that Ventolin® HFA, Flovent® HFA, Advair® Diskus, and Serevent® Diskus were approved by the FDA before the priority date does not mean that these devices met all the needs for an inhaler with a dose counter that existed as of the priority date. Indeed, as I explain above, these devices fail to meet combinations of two or more of the claimed properties—including superior functionality, accuracy (including, with respect to over- and under-counting), reliability, maintainability (and ability to be cleaned), robustness, manufacturability, minimal impact on device performance, and human factors—of the Asserted Claims.

54. Moreover, Mr. Anderson takes issue with my criticism of imprecise dose indicators because the FDA Guidance "explicitly references dose indicators as an acceptable option." Anderson Rebuttal Rep. on Secondary Considerations ¶ 31. Mr. Anderson also states

that my reliance on Conner 2013[1] is misplaced because, according to Mr. Anderson, "Conn[e]r 2013 makes clear that only certain types of dose indicators are considered to be less precise," and "Conn[e]r 2013 post-dates the Asserted Patents and therefore does not reflect any long felt, unmet need at the time of the invention." Anderson Rebuttal Rep. on Secondary Considerations ¶ 31. In addition, Mr. Anderson states that "there were numerous inhalers on the market at the time of the priority date of the asserted patents and at the time of Conn[e]r 2013, and none of these solely used color coded or indicator symbols." Anderson Rebuttal Rep. on Secondary Considerations ¶ 31.

55. Mr. Anderson's arguments are misplaced. As I explain above, in my opinion, the 2003 FDA Guidance sets out a minimum baseline in terms of the properties every inhalation device on the market should include. That the 2003 FDA Guidance establishes the minimum baseline regarding counting mechanisms such as dose indicators does not mean that the 2003 FDA Guidance addressed all of the multiple, specific, long-felt needs that existed as of the priority date. Nor does it mean that companies should have (or would have) ignored those needs in designing their products.

56. That the 2003 FDA Guidance sets only a minimum baseline is confirmed by the literature that I cite throughout my reports. Although Mr. Anderson criticizes my reliance on Conner 2013, in fact that reference supports my opinions. Conner 2013 discusses the shortcomings of dose indicating devices, including devices that were on the market as of the priority date, *see* Panettieri Opening Rep. § VI.A.2 (¶ 66), that use color coded display or indicator symbols, s*ee* Conner 2013[2] ("Dose indicators that rely solely on color coded display or

[1] TEVADOC-00000312.

[2] TEVADOC-00000312, at -315.

indicator symbol . . . are less precise than dose counters that use a numeric display . . . ."). As I explain in my Opening Report, the devices that relied on dose indicators using various colors were not effective for patients who were color blind. In my experience treating patients, a significant number of males are color blind. Such color-blind patients have reported that it was difficult for them to discern the colors on the dose indicators and to read the font sizes on those prior art devices. These issues had not been resolved as of the priority date. Moreover, even the dose indicators that were available or disclosed as of the priority date that used a numeric display, had shortcomings. As I explain in my Opening Report, those devices and disclosures did not report to the patients the precise number of doses remaining in their inhalers, and therefore did not meet the need in the art for an accurate, precise dose counter. *See* Panettieri Opening Rep. § VI.A.2 (¶¶ 65-68).

57. Finally, Mr. Anderson asserts that I "ignore[] that many of the[] references [I cited in my Opening Report] do track each dose dispensed (and therefore each dose remaining)." Anderson Rebuttal Rep. on Secondary Considerations ¶ 32. Specifically, he opines that:

> the Sapphire patent (U.S. 6,615,827) discloses that it "provides for easy and accurate dosage monitoring of the medicament . . . as a single dose." It further indicates that the device displays "the number of doses dispensed." The Senetics patent (U.S. 5,718,355) provides another example. The patent also describes an embodiment in which the indicator wheel has indicia viewable through a window in the outer cover to indicate the progressive rotation of the indicator wheel. "The indicia may be in the form of a sequence of numbers." Dr. Panettieri seemingly does not opine that the numerical sequence must display every dose given that Plaintiffs' own Qvar and ProAir products only numerically display every other dose. Thus, there is no functional difference between the disclosures of Senetics and the devices Plaintiffs contend fall within the scope of the asserted patents. This is confirmed by Plaintiffs' construction of "counter display arranged to indicate dose information" as "a component of the dose counter that display information regarding the number of doses remaining."

Anderson Rebuttal Rep. on Secondary Considerations ¶ 32 (citations omitted).

58. I disagree with Mr. Anderson. To begin with, U.S. Patent No. 6,615,827 (the "'827 Patent") discloses a "level indicator" that "slidably extends through a longitudinal slot in the housing" in order to indicate the "remaining amount of medicament." *See* '827 Patent, 3:35-37, Abstract. In my experience as a treating physician in the field of pulmonary medicine, some patients, especially the elderly or those with vision problems, have issues with devices that rely on these types of slidable indicators for several reasons: for example, (1) the device might not be tracking the number of remaining doses in a numerical form, and (2) even if it did, it is not easy for these patients to discern the number of remaining doses by relying on this slidable indicator. Moreover, Mr. Anderson's reliance on the "dose indicator" disclosed in the '827 Patent, *see* 3:55-57, is misplaced. The '827 Patent states that the "dose indicator device can be reset to zero by" rotating the device. '827 Patent, 4:9-14. In my opinion as a treating physician in the field of pulmonary medicine, devices that permit patients to reset the counting mechanisms can be unreliable and provide the incorrect dosage information to patients who do not always remember when they reset their mechanisms.

59. Mr. Anderson's reliance on U.S. Patent No. 5,718,355 (the "'355 Patent") is also misplaced. As Mr. Anderson points out, the patent merely states that the indicia on the indicator wheel "may be in the form of a sequence of numbers." Anderson Rebuttal Rep. on Secondary Considerations ¶ 32 (quoting '355 Patent, 4:45-50). Nowhere does the '355 Patent disclose what that sequence of numbers entails. As I explain in my Opening Report, mechanisms like the one disclosed in the '355 Patent simply "provide[] an indication of whether the canister [is] near full, near empty, or somewhere else in-between, or else provide[] more general information about the number of uses that had occurred." Panettieri Opening Rep. § VI.A.2 (¶ 66). These types of

mechanisms can lead patients to "have to estimate the number of uses remaining, risking under- or over-estimation." Panettieri Opening Rep. § VI.A.2-3 (¶ 85).

60. Additionally, Mr. Anderson mischaracterizes the properties of Qvar® HFA with dose counter and ProAir® HFA with dose counter. As I explain in my Opening Report, Qvar® HFA with dose counter and ProAir® HFA with dose counter are superior because they include precise dose counters as opposed to imprecise dose indicators that merely provide an indication of whether the canister was near full, near empty, or somewhere in-between, or else provide more general information about the number of uses that have occurred. As a result, the dose counters included in Qvar® HFA with dose counter and ProAir® HFA with dose counter provide patients with more time to plan to replace their medicament canisters. Consequently, patients who use Qvar® HFA with dose counter and ProAir® HFA with dose counter do not have to estimate the number of uses remaining, risking under- or over-estimation.

61. To support his assertion that the devices disclosed by the '827 Patent and '355 Patent fall within the scope of the Asserted Claims, Mr. Anderson appears to raise a claim construction dispute. I have been informed that the parties have proposed different constructions for the term "counter display arranged to indicate dosage information." I have been informed that Teva proposed that the term should be construed according to its plain and ordinary meaning, in view of the claims, specification, and prosecution history, to mean "a component of the dose counter that displays information regarding the number of doses remaining." I have been informed that Defendants propose that the terms should be construed to mean "structure displaying the number of doses remaining." I have not been asked to provide an opinion about which construction is correct, and I express no opinion on that issue.

62. Nevertheless, in my opinion, the devices disclosed by the '827 Patent and '355 Patent do not satisfy the needs for dose counters recited in the claims. As I explain below in greater detail, although Mr. Anderson focuses on the phrase "counter display," he ignores that the claimed inventions require "dose counters." Irrespective of the claim construction issues raised by Mr. Anderson, the dose indicating devices disclosed in the '827 and '355 Patents fall well short of what the Asserted Claims require. I therefore disagree with Mr. Anderson.

2. Mr. Anderson Is Incorrect That the Identified Needs Were Addressed as of the Priority Date

63. Mr. Anderson asserts that the references I relied on in my Opening Report fail to support my "opinions that the asserted patents solved . . . alleged needs" in the industry. *See* Anderson Rebuttal Rep. on Secondary Considerations ¶ 33. For the reasons set out in my Opening Report and below, I disagree with Mr. Anderson.

a. 2003 FDA Guidance

64. Mr. Anderson states that there are multiple problems with my reliance on the 2003 FDA Guidance. Anderson Rebuttal Rep. on Secondary Considerations ¶¶ 34-39. For the reasons set out in my Opening Report and below, I disagree with Mr. Anderson.

65. To begin with, Mr. Anderson asserts that the FDA Guidance was published in 2003, "six years before the alleged priority date of the asserted patents." Anderson Rebuttal Rep. on Secondary Considerations ¶ 34. Mr. Anderson also states that:

> Dr. Panettieri does not address the six years of development that occurred between the publication of this guidance and development of the dose counter claimed in the asserted patents. As a result, he ignores that by 2009 there were numerous dose counters available that addressed any needs identified by the FDA's 2003 Guidance. Teva's corporate designee agreed. By 2009 (prior to the alleged priority date of the asserted patents), dose counters were generally incorporated into inhalers. By 2009-2010, the incorporation of dose counters was outright commonplace. Today their use is ubiquitous. There are numerous different types of dose counters, yet the dose

> counters of the asserted patents have been used in only two products (one of which has been discontinued).

Anderson Rebuttal Rep. on Secondary Considerations ¶ 34; *see also* Anderson Opening Rep. ¶ 472 (noting that "[b]y May 2010, dose counters were commonly incorporated in inhalers" and that "dose counter claimed in the Asserted Patents is found in just two products (one of which has been discontinued").

66. I disagree with Mr. Anderson. First, the fact that the FDA Guidance was published in 2003 does not mean that by 2009, there was a product on the market that addressed the needs that I identified in my Opening Report. Indeed, as I explain at length in my Opening Report, prior art devices and disclosures did not meet the need in the art for an accurate, precise dose counter, because they did not report to patients the precise number of doses remaining in their inhalers. *See* Panettieri Opening Rep. § VI.A.2 (¶¶ 65-68). Instead, counting mechanisms used at the time, such as dose indicators, provided an indication of whether the canister was near full, near empty, or somewhere in-between, or else provided more general information about the number of uses that had occurred. Moreover, dose indicators do not satisfy the need for accurate, precise dose counters and are inferior because they do not allow as much planning for patients to replace their medicament canisters as precise, accurate dose counters do. Consequently, patients using inhalers with dose indicators had to estimate the number of uses remaining, risking under- or over-estimation.

67. In my experience, dose indicators did not precisely convey the number of remaining doses to a patient. In the absence of such information, a patient would need to guess the number of remaining doses in a canister. Moreover, the devices that relied on dose indicators using various colors were not effective for patients who were color blind. In my experience treating patients, a significant number of males are color blind. And color-blind patients stated

that it was difficult for them to discern the colors on the dose indicators and to read the font sizes on those prior art devices. These issues had not been resolved as of the priority date.

68. Moreover, Defendants' documents acknowledge that the 2003 FDA Guidance recognized several problems with devices that were on the market as of the priority date. *See, e.g.*, CIPLA-BDI_0783819 ("Cipla Dose Counters" Deck) at CIPLA-BDI_0783823-27 (setting out recommendations in 2003 FDA Guidance) and at CIPLA-BDI_0783843, CIPLA-BDI_0783845 (recognizing problems with prior art, including lack of "reliable method by which a patient could determine whether any drug remained in their [p]MDI").

69. Moreover, contrary to Mr. Anderson's assertion, I did describe several prior art references and disclosures that were developed between 2003 and 2009. *See, e.g.*, Panettieri Opening Rep. § VI.A (¶¶ 45-82). And, as I explain above, the prior art devices that Mr. Anderson relies on in Section XI.A of his Rebuttal Report on Secondary Considerations do not meet the multiple, specific, long-felt needs that I identified in my Opening Report. *See supra* § VI.A.1. The fact that these and other products incorporated counting mechanisms does not mean that those mechanisms were reliable, precise, and/or accurate or met the other needs satisfied by the claimed inventions.

70. Moreover, contrary to Mr. Anderson's suggestion, Teva did not discontinue one of the products that embodied the Asserted Patents because of problems with the claimed inventions. Rather, I understand that Teva discontinued that product due to "business reasons, unrelated to the well-established safety and effectiveness of the product." TEVAQVAR-00015375. In my experience, those kinds of business-related decisions are common in the inhalation aerosol industry, and it is not uncommon for a company to introduce multiple devices in a relatively short timeframe.

71. Additionally, Mr. Anderson states that the 2003 FDA Guidance "is generic" and states that:

> [The 2003 FDA Guidance] recommend[s] that manufacturers include any type of dose counter that provides "either through a direct numeric count or color coding, a clear indication of when an MDI is approaching the end of its recommended number actuations as well as when it has reached or exceeded that number." Ironically, Dr. Panettieri goes on to criticize dose counters that used color indicators despite the FDA's guidance that these are acceptable. Dr. Panettieri cannot both rely on the FDA's guidance as identifying problems and then criticize the very solution that the FDA identified for that problem.

Anderson Rebuttal Rep. on Secondary Considerations ¶ 36 (citations omitted).

72. I disagree with Mr. Anderson. In my opinion, the 2003 FDA Guidance sets out a baseline in terms of what properties every inhalation device on the market should include. That said, the fact that the 2003 FDA Guidance establishes the minimum baseline does not mean that the 2003 FDA Guidance addressed the multiple, specific, long-felt needs that existed as of the priority date. Nor does it mean that companies should have ignored those needs in designing their products. Both the baseline requirement and the multiple, specific long-felt needs were important to designing a dose counter.

73. Mr. Anderson also states that the "recommendations cited in the bullet points in Paragraph 55 of the Panettieri Report are also generic, reciting basic recommendations such as counting downward rather than upward, reliably tracking actuations, avoiding undercounting, and conducting in vitro studies." Anderson Rebuttal Rep. on Secondary Considerations ¶ 37. In Mr. Andersons' view, I do "not identify a specific need that would be solved by the dose counter of the asserted patent that would not have been solved by any other dose counter." Anderson Rebuttal Rep. on Secondary Considerations ¶ 37. I disagree with Mr. Anderson. In my Opening

Report, I identified several specific, long-felt needs that had not been met by prior art devices or disclosures as of the priority date. *See* Panettieri Opening Rep. § VI.A (¶¶ 45-82).

74. In addition, Mr. Anderson states that "Teva's corporate designee testified that by 2009 there were devices on the market that addressed any needs identified in the FDA guidance, but Teva's 'products, both Qvar® and ProAir®, . . . still had not addressed the need. Thus, by 2009, these needs were specific to Teva, not the industry at large." Anderson Rebuttal Rep. on Secondary Considerations ¶ 39 (citations omitted). I disagree with Mr. Anderson's characterization of Mr. Walsh's testimony. The fact that dose counters and other counting mechanisms were on the market as of the priority date does not mean that those products satisfied the 2003 FDA Guidance, let alone the multiple, specific, long-felt needs that I identified in my Opening Report. *See* Panettieri Opening Rep. § VI.A (¶¶ 65-82).

b. Ogren 1995, Broeders 2009, Sander 2006, Hess 2008, Holt 2005, Fink 2005, '021 Publication, and Williams 1999

75. Mr. Anderson criticizes my reliance on Ogren 1995,[3] Sander 2006,[4] Hess 2008,[5] Holt 2005,[6] Fink 2005,[7] '021 Publication, and Williams 1999.[8] *See* Anderson Rebuttal Rep. on Secondary Considerations ¶¶ 40–41. According to him, these references "merely identify[] the generic desirability of a dose counter." ¶ 40. I disagree with Mr. Anderson.

[3] TEVADOC-00000011.

[4] TEVADOC-00000046.

[5] TEVADOC-00000379.

[6] TEVADOC-00000406.

[7] CIPLA-BDI_0784184.

[8] TEVADOC-00000744.

76. Contrary to Mr. Anderson's assertions, these references identified multiple, *specific*, long-felt needs, *see, e.g.*, Panettieri Opening Rep. § VI.A (¶¶ 56-63):

- For example, they recognized the need for inhalers with dose counters that were accurate over the life of the inhaler. *See, e.g.*, '021 Publication, ¶ [0006] (stating that indicating devices with "complex moving parts" may be "susceptible to counting inaccuracies due to the configuration of the indexing or mating parts"); Hess 2008[9] (noting that some devices "occasionally recorded additional actuations," and that, "[o]ver time," showed a "trend toward decreasing accuracy"); *id.* (noting that some devices did not "record[] actuations after the preset counter reaches zero, which leads to premature arrival of the counter at zero and subsequent inability to record further doses"); *id.* (noting that some devices showed a trend in decreasing accuracy as a result of "battery decay").

- These prior art reference recognized the need for inhalers with accurate and precise dose counters. *See, e.g.*, 2003 FDA Guidance[10]; *see also, e.g.*, Holt 2005[11]; Sander 2006[12] Ogren 1995[13]; Fink 2005[14]; Hess 2008[15]; Broeders 2009.[16]

- These prior art references recognized the need for inhalers with dose counters that had superior functionality and minimal impact on device performance. *See, e.g.*, '021 Publication, ¶ [0006] (noting that some indicating devices "may impede or interfere with the airflow and medicament being dispensed from the inhalation device"); *id.* (noting that some indicating devices may "require a power source" in order to function).

- These prior art references recognized a need for inhalers with dose counters that had the manufacturability of the claimed inventions. *See, e.g.*, '021 Publication, ¶ [0006]. (stating that indicating devices "may include complex moving parts which can be difficult to assemble and expensive to manufacture").

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[9] TEVADOC-00000379, at -391.

[10] TEVAQVAR-00032573, at -577.

[11] TEVADOC-00000406, at -407.

[12] TEVADOC-00000046, at -49-50.

[13] TEVADOC-00000011, at -14-15.

[14] CIPLA-BDI_0784184, at -189.

[15] TEVADOC-00000379, at -390.

[16] TEVADOC-00000001, at -03.

- These prior art references recognized the need for inhalers with dose counters that did not add bulk to or otherwise change the appearance of the inhalers with which patients were already familiar, and that did not change the manner in which patients used their inhalers. *See, e.g.*, '021 Publication, ¶ [0006] (noting that indicating devices with "complex moving parts" may "require excessive amounts of space within the housing to accommodate the relatively large or numerous moving parts"); Williams 1999[17] (noting that when patients hold some devices, the distance "between the thumb and forefinger" "may be too far for some patients to actuate comfortably," and that this "may be difficult, especially for arthritic patients, children, or other persons with small hands"); Hess 2008[18] (explaining that add-on electronic counting mechanisms "add to the cost" and "complexity of therapy because they add a device to the treatment regimen"); Fink 2005[19] (explaining that "[t]hird-party counting devices are available, but add additional expense").

- These prior art references recognized the need for inhalers with dose counters that were easily maintainable and could be cleaned. *See, e.g.*, '289 Patent, 2:33-35 ("Additionally, it is felt desirable to improve upon inhalers by making them easily usable after they have been washed with water"); '021 Publication, ¶ [0006] (noting that some indicating devices "may be susceptible to damage in various environments, such as moist conditions").

77. In addition, Mr. Anderson asserts that because these references were written or published before the priority date, "these references cannot possibly take into account the state of the industry" at the time of the priority date. Anderson Rebuttal Rep. on Secondary Considerations ¶ 40; Anderson Opening Rep. ¶ 472 (similar). I disagree with Mr. Anderson.

78. Based on my personal experience as a treating physician in the field of pulmonary medicine, the needs identified in Ogren 1995, Sander 2006, Hess 2008, Holt 2005, Fink 2005, '021 Publication, and Williams 1999 had not been met as of the priority date. As I explain in my Opening Report, those needs included the need for inhalers with dose counters that had sufficient functionality, accuracy (including with respect to under- and over-counting), reliability,

[17] TEVADOC-00000744.

[18] TEVADOC-00000379, at -391.

[19] CIPLA-BDI_0784184, at -189.

maintainability (and ability to be cleaned), robustness, manufacturability, minimal impact on device performance, and human factors (including aesthetics, ergonomics, and other human factors). *See* Panettieri Opening Rep. § VI (¶¶ 45-82).

79. Moreover, Mr. Anderson asserts that Ventolin® HFA, Flovent® HFA, Serevent® Diskus, Advair® Diskus, and Dulera® met the multiple, specific, long-felt, unmet needs that I identified in my Opening Report. Anderson Rebuttal Rep. on Secondary Considerations ¶¶ 40-41. However, as I discuss in more detail above, these devices did not satisfy the multiple, specific, long-felt, unmet needs that existed in the industry as of the priority date. *See supra* § VI.A.1.

80. Moreover, Mr. Anderson asserts that Hess 2008 "supports Defendants' position" because "Hess describes dose counters used in the Ventolin HFA and Flovent HFA, as well as add-on dose counters that can be used with inhalers, such as the Doser and the MD Turbo." Anderson Rebuttal Rep. on Secondary Considerations ¶ 41. Mr. Anderson further states that I did not "address [a] portion of Hess" that discussed "an article by Seth published in 2006 that evaluated a pMDI with an integrated dose counter." Anderson Rebuttal Rep. on Secondary Considerations ¶ 41. He further states that I did not "present any opinion that the dose counters discussed by these publications were not accurate reliable, safe, effective, or robust." Anderson Rebuttal Rep. on Secondary Considerations ¶ 41. I disagree with Mr. Anderson for several reasons.

81. First, Hess 2008 does not "support[] Defendants' position." As I discuss above and in my Opening Report, Hess 2008 recognized several problems in the prior art. Panettieri Opening Rep. ¶¶ 57, 62, 78; *see, e.g.*, Hess 2008[20] (noting that some devices "occasionally

[20] TEVADOC-00000379, at -391.

recorded additional actuations," and that, "[o]ver time," showed a "trend toward decreasing accuracy"); *id.* (noting that some devices did not "record[] actuations after the preset counter reaches zero, which leads to premature arrival of the counter at zero and subsequent inability to record further doses"); *id.* (noting that some devices showed a trend in decreasing accuracy as a result of "battery decay"); *id.* (explaining that add-on electronic counting mechanisms "add to the cost" and "complexity of therapy because they add a device to the treatment regimen"). As I discuss in my Opening Report, these problems existed as of the priority date and had not been addressed by devices or disclosures in the prior art. *See* Panettieri Opening Rep. § VI.A (¶¶ 56-63).

82. Moreover, as I discuss above, Mr. Anderson's reliance on Ventolin® HFA and Flovent® HFA is misplaced. *See supra* § VI.A.1.b. Mr. Anderson is also incorrect with respect to the Doser and MD Turbo™. As I explain in my Opening Report, the Doser and MD Turbo™ present several drawbacks. Panettieri Opening Rep. ¶ 76. For example, the Doser and MD Turbo™ devices are not "integrated" and are simply an add-on, *see* Hess 2008[21] (MD Turbo™); Lewis 2007[22] (MD Turbo™), which presents problems for patients. "[T]he use of an add-on device undermines the portability advantages of the [p]MDI" and makes the device "bulk[y]" which "may result in non-compliance in patient use." Lewis 2007, CIPLA-BDI_0184747, at -749-50.

83. As I explain in my Opening Report, in my experience as a physician, devices that are bulky are less attractive from an ergonomic perspective for patients because they are more difficult to actuate. As a result, many of these patients would be less likely to use the inhaler on

[21] TEVADOC-00000379, at -390-91.

[22] CIPLA-BDI_0184747, at -750.

a consistent basis. Moreover, when the counting mechanism was an add-on device, patients would often remove the add-on device in order to fit the inhaler in their pockets. This, in turn, created a number of other issues. For example, patients would lose the add-on devices and thereby would lose track of the number of doses remaining in a canister. By way of further example, a patient would also damage the add-on device, rendering them unreliable. *See, e.g.*, Panettieri Opening Rep. ¶ 58.

84. Finally, Mr. Anderson is incorrect that I "d[id] not address" the type of pMDI—namely, GlaxoSmithKline's Advair® HFA with dose counter—discussed in a 2006 article published by Sheth. Nowhere does Sheth, let alone Mr. Anderson, explain that the integrated dose counter discussed in Sheth satisfied a combination of specific, long-felt needs in the field of pulmonary medicine, including, the needs for inhalers with dose counters that had sufficient functionality, accuracy (including with respect to under- and over-counting), reliability, maintainability (and ability to be cleaned), robustness, manufacturability, minimal impact on device performance, and human factors (including aesthetics, ergonomics, and other human factors). Moreover, Sheth discusses Advair® HFA with dose counter, a device which includes its counting mechanism near the boot of the inhalation device. And, as I explain above and in my Opening Report, devices that have counting mechanism attached to the canister valve and are situated near the boot of the inhaler body affect usability and may disrupt air flow. In my experience as a treating physician, patients may not receive adequate inhalation medication if they are using a device with such counting mechanisms.

85. I also note that Sheth 2006 was supported by GlaxoSmithKline and investigators and speakers sponsored by GlaxoSmithKline. While this in and of itself does not undermine Mr. Anderson's reliance on Sheth 2006, I note that Mr. Anderson attempts to undermine my reliance

on Chipps and Given by pointing to the source of their funding (Teva). In any event, there are several reasons why the study in Sheth 2006 is flawed. To begin with, the study only recruited individuals who could use the device. In my experience as a practicing physician, however, patients who are prescribed inhaler devices do not always use them correctly or appropriately. Moreover, while the results show that 95% of patients were satisfied with the inhaler device with dose counter, that figure is only a marginal increase from the 81% of patients who were satisfied with the inhaler device without dose counter. Ultimately, these additional reasons undermine the strength of the results in Sheth 2006, and Mr. Anderson's reliance on this study is misplaced.

c. Problems Posed by MDIs Lacking Dose Counters and Related Patient Behavior Are Not Irrelevant

86. Mr. Anderson asserts that I rely on "pre-dose counter tests," and that the "needs [I] identif[y] are generic and would be solved by any dose counter." Anderson Rebuttal Rep. on Secondary Considerations ¶¶ 42-43. He further states that this need does not "relate specifically to a need solved by the dose counters claimed in the asserted patents." Anderson Rebuttal Rep. on Secondary Considerations. ¶¶ 42-43. I disagree with Mr. Anderson.

87. To begin with, in my experience as a treating physician in the field of pulmonary medicine, patients continued to use these "pre-dose counter tests" as of the priority date even after companies implemented counting mechanisms in their inhalers because these counting mechanisms were not sufficiently precise, accurate, reliable, or usable.

88. Indeed, as I explain in my Opening Report, several devices and disclosures in the prior art did not meet the need for an accurate, precise dose counter, because they did not report to patients the precise number of doses remaining in their inhalers. Panettieri Opening Rep. § VI.A.2.a (¶¶ 65-68). Instead, counting mechanisms in the prior art provided an indication of whether the canister was near full, near empty, or somewhere in-between, or else provided more

general information about the number of uses that had occurred. *See*, e.g., Stuart 2013[23] ("[Dose indicators] often do not index every count and require some patient interpretation of the display . . . . [Dose indicators] are not considered by patients to be as accurate as dose counters."); Conner 2013[24] ("Dose indicators that rely solely on a color coded display or indicator symbol . . . are less precise than dose counters that use a numeric display . . . ."). The Asserted Patents reflect a desire to improve upon such dose indicating devices in prior art by providing "extremely accurate dose counters." '289 Patent, 2:9-12.

89. The counting mechanisms available as of the priority date did not satisfy the need for accurate, precise dose counters and were inferior because they do not allow as much planning for patients to replace their medicament canisters as precise, accurate dose counters do. Consequently, patients using inhalers with dose indicators, for example, had to estimate the number of uses remaining, risking under- or over-estimation. *See, e.g.*, Stuart 2013.[25] Estimating the number of uses remaining could lead to patients doing two things: (1) "throw[ing] away a[p]MDI that may still contain acceptable metered-doses," thereby leading to waste; or (2) "us[ing] a product when it may be beyond recommend number of doses and risk not receiving

[23] TEVADOC-00000531, at -531.

[24] TEVADOC-00000312, at -315.

[25] TEVADOC-00000531, at -531-32.

the correct drug use." 2003 FDA Guidance[26]; *see also, e.g.*, Holt 2005[27]; Sander 2006[28]; Ogren 1995[29]; Fink 2005[30]; Hess 2008.[31]

90. As I explain in my Opening Report, in my experience treating patients with asthma and COPD, I frequently observed the problems that resulted from the lack of a reliable and/or accurate dose counter. By way of background, a medicament canister will continue spraying beyond the point where it runs out of the active drug. As a result, a patient may think that he or she has remaining doses in a canister simply because the inhaler sprays after an actuation. I treated several patients who, lacking a reliable and accurate dose counter, would often continue using their inhalers simply because the inhaler released a spray even if there was no longer any medication in the spray.

91. In my experience, the inability to accurately measure how much active drug remains in a canister could lead to medical emergency or waste. Several patients, for example, would replace their medicament canisters before it was necessary to do so and discarded medicament canister that still contained medication. Other patients would continue using their inhalers even though the medicament canisters did not contain any medication. If these patients were prescribed a maintenance medicine (i.e., beta antagonists) to treat asthma, they would have to resort to rescue therapies more often because they were not receiving sufficient maintenance

[26] TEVAQVAR-00032573, at -577.

[27] TEVADOC-00000406, at -407.

[28] TEVADOC-00000046, at -49-50.

[29] TEVADOC-00000011, at -14-15.

[30] CIPLA-BDI_0784184, at -189.

[31] TEVADOC-00000379, at -390.

medicine. Accurate and reliable dose counters, such as those in Qvar® HFA with dose counter and ProAir® HFA with dose counter, were critical in addressing these issues. In fact, many of my patients who did not use Qvar® HFA with dose counter and ProAir® HFA with dose counter would regularly lose track of how many doses remain in their devices.

92. In my experience, one of the important reasons to include an accurate and reliable dose counter in an inhaler is so that physicians like myself can ensure that patients are complying their recommended dosing regimen. For example, if a patient returns for a follow-up visit with me and brings his or her inhaler, I would review the dose counter. Maintenance inhaler use such as Qvar® should be used with two actuations twice daily. If the counter revealed less than the expected use, then I would be alerted that the patient has been non-adherent to the prescribed therapy. Additionally, if their rescue inhaler use (ProAir®) was higher than expected (2 puffs weekly) then these data would suggest the patient's asthma or COPD is under poor control. In both hypothetical situations, I, the prescriber, would alter the therapy.

93. In my experience, devices such as Qvar® HFA with dose counter and ProAir® HFA with dose counter enabled to patients to have more control in treating their medical conditions that led to fewer medical emergencies.

94. Moreover, the devices that relied on dose indicators that had various colors were not effective for patients who were color blind. In my experience treating patients, a significant number of males are color blind. And color-blind patients stated that it was difficult for them to discern the colors on the dose indicators and to read the font sizes of those prior art devices. Conversely, Qvar® HFA with dose counter and ProAir® HFA with dose counter were much more effective for these color-blind patients. The dose counters in these devices did not rely on dose counters and the font size was much easier for patients to discern.

95. As I explain in my Opening Report, the claimed inventions, as embodied in Qvar® HFA with dose counter and ProAir® HFA with dose counter, satisfied the needs for a dose counter with sufficient functionality, accuracy (including, with respect to under- and over-counting), reliability, robustness, and precision. *See* Panettieri Opening Rep. § VI.A.3 (¶¶ 83-96).

d. The Need for a Cleanable Inhaler Was Not Addressed By the Prior Art

96. Mr. Anderson asserts that I "repeatedly point[] to the alleged cleanability of the claimed inventions" but "fail[] to provide any nexus to the actual claims of the Asserted Patents." Anderson Rebuttal Rep. on Secondary Considerations ¶ 44; *see* Anderson Opening Rep. ¶ 477. Moreover, Mr. Anderson asserts that I "fail to address" the cleanability of other devices in the prior art, including the '406 Publication and a Bespak device. *See* Anderson Rebuttal Rep. on Secondary Considerations ¶ 45.

97. I disagree with Mr. Anderson. To begin with, I have been informed that nexus does not require that a claim expressly recite the advantages of a patented invention. As Dr. Lewis explains in his Reply Report, the combination of elements recited in the claims sets forth an inhalation device with an internal, precise, and accurate does counter that is situated in a counter chamber. *See* Lewis Reply Rep. § VI.A.1.b.4. Mr. Anderson appears to focus on the fact that the Asserted Patents do not use the terms "maintainability" or "ability to be cleaned" or similar phrases. That, however, is not what is important. Instead, the key is that the inventions recited in the Asserted Claims provide the unique combination of elements from which these advantages flow. It is not surprising that the Asserted Claims do not refer to these terms, given that the Asserted Claims describe the inventions in terms of their design. In my opinion, however, it is those designs that solved the needs I describe.

98. Mr. Anderson also states that, "[b]ased on how Plaintiffs interpret claims for infringement, Plaintiffs do not contend that the asserted claims require a separate dose counter chamber because one does not exist in Defendants' ANDA Products." Anderson Rebuttal Rep. on Secondary Considerations ¶ 44. To the extent that Mr. Anderson suggests that cleanability relates solely to the existence of a "separate counter chamber," I disagree with Mr. Anderson. As Dr. Lewis explains (Lewis Reply Rep. § VI.A.1.b.4), such advantages also flow from other claimed features of the inventions. Dr. Lewis's opinions are consistent with my own. In my experience, these features contribute to patients' ability to easily clean ProAir® HFA with dose counter and Qvar® HFA with dose counter.

99. Mr. Anderson is incorrect in opining that the '406 Publication and a Bespak device satisfied the needs of the claimed inventions, including maintainability (and the ability to be cleaned). Mr. Anderson states that the '406 Publication "would be equally cleanable" to the claimed inventions embodied in Qvar® HFA with dose counter and ProAir® HFA with dose counter. But, as Dr. Lewis explains in his Reply Report, Mr. Anderson fails to provide any support for his assertion. *See* Lewis Reply Rep. § VI.A.1.b.4. Nowhere do the claims, or any part of the '406 Publication require any combinations of features that facilitates maintainability (and ability to be cleaned).

100. I also disagree with Mr. Anderson's opinions regarding Mr. Declan Walsh's testimony. Mr. Anderson states that Mr. Declan Walsh "testified that a known Bespak device that included a dose counter would have been washable," and that "[h]e further testified that it is a characteristic of the inhaler that determines whether it needs washing, not the dose counter itself." Anderson Rebuttal Rep. on Secondary Considerations ¶ 45. Based on Mr. Anderson's interpretation of this testimony, Mr. Anderson concludes that "it is not clear what aspect of the

claimed inventions (which generally relate to dose counters) could impact cleaning." Anderson Rebuttal Rep. on Secondary Considerations ¶ 45. I disagree with Mr. Anderson.

101. To begin with, Mr. Anderson mischaracterizes Mr. Walsh's testimony. Mr. Walsh was asked: "Was – is the Bespak *dose counter* cleanable?" Walsh Dep. Tr. 194:21-22. In response to this question, Mr. Walsh testified: "[S]o there is no dose counter that I am aware of where people are instructed to wash the *dose counter*. There are inhalers with drug products on the marker and the *inhaler itself* requires washing occasionally to maintain its pharmaceutical performance. So is the Bespak dose counter cleanable? You could wash it. You could introduce it to water. Why would you do it? I don't know." Walsh Dep. Tr. 195:15-:196:2 (emphases added). That the Bespak device could have been introduced to water does not mean that the Bespak device had the properties of the claimed invention—specifically, their maintainability (and ability to be cleaned). Moreover, nothing about Mr. Anderson's statement that the inhaler itself (as opposed to the dose counter in the device) needs to be washed is inconsistent with my opinion regarding the characteristics of the claimed inventions, including their superior maintainability. The scope of the Asserted Claims relate to several aspects of the dose counter, including its position within and relative to other components inside of the inhaler. These features of the Asserted Claims are what facilitate the maintainability (and ability to be cleaned) of the claimed inventions.

3. Qvar® HFA and ProAir® HFA Satisfied Multiple, Long-Felt Needs

102. Mr. Anderson asserts that there are "numerous issues" with respect to my opinion that "Teva's commercial products"—*i.e.*, Qvar® HFA with dose counter and ProAir® HFA with dose counter—"allegedly satisfied long-felt needs." Anderson Rebuttal Rep. on Secondary Considerations ¶ 46. For the reasons set forth in my Opening Report and below, I disagree with Mr. Anderson.

103. To begin with, Mr. Andersons repeats his assertion that I "ignore[d] the prior art dose counters discussed in Section XI.A [in Anderson's Rebuttal Report on Secondary Considerations] that would have addressed any of these alleged needs." Anderson Rebuttal Rep. on Secondary Considerations ¶ 47. However, as I explain above, Mr. Anderson's reliance on the dose counters set forth in Section XI.A of his Rebuttal Report on Secondary Considerations is misplaced. *See supra* § VI.A.1.

a. Mr. Anderson's Focus on Claim Construction Issues Is Misplaced

104. Mr. Anderson states that my opinion "ignores the scope of the claims of the asserted patents (at least as Plaintiffs are interpreting them in this action)." Anderson Rebuttal Rep. on Secondary Considerations ¶ 48. Specifically, he states:

> Dr. Panettieri opines that Qvar and ProAir "included precise dose counters as opposed to imprecise dose counters that merely provided an indication of whether the canister was near full, near empty, or somewhere in-between." He further criticizes dose counters that rely on color to indicate dosage information. But Plaintiffs contend that the term "counter display" in the '808 patent merely means "a component of the dose counter that displays information regarding the number of doses remaining." Dose counters that provide any indication of "whether the canister was near full, near empty, or somewhere in-between" or provide color indicators would fall within the scope of Teva's interpretation of "counter display" in the '808 patent. Thus, even if Qvar and/or ProAir provided one type of dosage information, the asserted patents are broader and claim nothing more than the types of dose indication that are in the prior art.

Anderson Rebuttal Rep. on Secondary Considerations ¶ 48 (citations omitted).

105. I disagree with Mr. Anderson. To begin with, Mr. Anderson is incorrect that "[d]ose counters . . . that provide color indicators would fall within the scope of Teva's interpretation of 'counter display' in the '808 patent." In offering his opinion, Mr. Anderson appears to raise a claim construction dispute. I have been informed that the parties have

proposed different constructions for the term "counter display arranged to indicate dosage information." I have been informed that Teva proposed that the term should be construed according to its plain and ordinary meaning, in view of the claims, specification, and prosecution history, to mean "a component of the dose counter that display information regarding the dosage remaining." I have been informed that Defendants propose that the terms should be construed to mean "structure displaying the number of doses remaining." I have not been asked to provide an opinion which construction is correct, and I express no opinion on this issue.

106. Nevertheless, in my opinion, Mr. Anderson's focus on the parties' dispute over the term "counter display" is misplaced. Although Mr. Anderson focuses on that term, he ignores that the claimed inventions require "dose counters," not dose indicators. As such, it is clear that the claimed inventions do not cover "the types of dose *indication* devices" that are in the prior art. Consequently, Mr. Anderson is incorrect that "[d]ose counters that provide any indication of 'whether the canister was near full, near empty, or somewhere in between' . . . would fall within the scope of Teva's interpretation of 'counter display' in the '808 patent."

107. Mr. Anderson also asserts that "a lack of electrical circuity is not a requirement of any claim of the asserted patents," and that "the ergonomics and cleanability of the inhaler are . . . not required by any of the asserted claims." Anderson Rebuttal Rep. on Secondary Considerations ¶¶ 49-50. As such, Mr. Anderson concludes that the "alleged satisfaction of long-felt needs lack the requisite nexus to the patent claims." Anderson Rebuttal Rep. on Secondary Considerations ¶ 50; *see* Anderson Opening Rep. ¶ 477.

108. I disagree with Mr. Anderson. To begin with, I have been informed that nexus does not require that a claim expressly recite the advantages of a patented invention. In any

event, as I explain above (*see supra* § VI.A.2.d), there is a nexus between ergonomics and cleanability and the Asserted Claims.

109. Moreover, as Dr. Lewis explains in his Reply Report, the combination of elements recited in the claims set forth a metered dose inhaler that is operated by the hand movement of a user rather than being operated by electronic components. *See* Lewis Reply Rep. § VI.A.1.c. For example, the Asserted Claims recite several mechanical components. *See, e.g.*, '289 Patent, Claim 1 (reciting "operation by movement of the medicament canister"); '587 Patent, Claims 1, 12-13 (similar); '156 Patent, Claim 1 (reciting mechanical components such as "ratchet wheel," "actuator pawl," and "count pawl"). Moreover, the '808 Patent also refers to "regulating motion" of the counter display "in response to actuation input." As Dr. Lewis explains, these mechanical features make sense only in the context of a mechanical dose counter, not an electronic dose counter. *See* Lewis Reply Rep. § VI.A.1.c.1.

110. It appears that, in his Report, Mr. Anderson focuses narrowly on the fact that the Asserted Patents do not use the phrase "lack of electrical circuitry" or similar phrases. That, however, is not what is important in this analysis. Instead, what is important is that the inventions recited in the Asserted Claims provide the unique combination of elements from which these advantages flow. It is not surprising then that that Asserted Claims do not use those phrases expressly because they describe the inventions in terms of their design. In my opinion, however, it is those designs that solved the needs I describe.

111. As I explain in my Opening Report, there are several advantages to having an inhalation device that does not require electronic components. *See* Panettieri Opening Rep. § VI.A.2.c. (¶¶ 75-82). For example, I noted that as of the prior art, many dose counters contained complicated electronic components and consequently, were useful only for very

limited purposes and/or had limited reliability, manufacturability, and/or ergonomic value. *See* Panettieri Opening Rep. § VI.A.2.c (¶¶ 75-82). Indeed, in my practice, I did not regularly prescribe electronic devices because they were and continue to be too expensive for patients. Insurance companies generally do not cover the cost of these devices, making them cost prohibitive for most patients. Most of my patients did not want or could not pay for expensive inhalers. In my experience as a treating physician, patients are less likely to adhere to a medication regimen when there are features on their inhalation devices that reduce ergonomic and/or aesthetic value, increase cost of therapy, and/or render the device less reliable with time. Unlike devices in the prior art, Qvar® HFA with dose counter and ProAir® HFA with dose counter, which embody the Asserted Claims, did not have the drawbacks that existed in inhalation devices with electronic components.

b. Mr. Anderson's Criticisms of Given 2012 and Chipps 2017 Are Incorrect

112. Mr. Anderson asserts that Given 2012 and Chipps 2017 "regarding the functionality and features of the Qvar and ProAir devices" fail to support my conclusion that Qvar® HFA with dose counter and ProAir® HFA with dose counter satisfied the long-felt, unmet needs that I identified. *See* Anderson Rebuttal Rep. on Secondary Considerations ¶ 52; Anderson Opening Rep. ¶ 475. For the reasons set out in my Opening Report and below, I disagree with Mr. Anderson.

113. To begin with, Mr. Anderson seeks to undermine these studies by pointing out that Teva funded them. *See* Anderson Rebuttal Rep. on Secondary Considerations ¶ 52; Anderson Opening Rep. ¶ 475. That Teva funded these studies, however, does not mean that the funding created any bias. Indeed, nowhere in his Report does Mr. Anderson identify a single deficiency in the studies or the experimental designs. Moreover, I am familiar with the

scholarship of Chipps and Given, both of whom are world-renowned in the field of pulmonary medicine. In my opinion, his studies are well-designed and robust, and the results from these studies stand up to the scrutiny, analysis, and replication demanded by the scientific community.

114. Moreover, according to Mr. Anderson, "in the Given 2012 study, the only dose counter used was the ProAir HFA MDI, so this study could not conclude that the dose counter was more reliable or accurate than existing dose counters." Anderson Rebuttal Rep. on Secondary Considerations ¶ 52; Anderson Opening Rep. ¶ 475 (similar). He further opines that "the Chipps 2017 study concluded only that ProAir HFA with a dose counter had 'lower healthcare resource use including all-cause and respiratory-related and inpatient and ED visits, higher refill rates, and fewer exacerbations.'" Anderson Rebuttal Rep. on Secondary Considerations ¶ 52; Anderson Opening Rep. ¶ 475 (similar). In Mr. Anderson's view, "[n]either of these studies concludes that the dose counter addressed some need in the industry that the prior art had not addressed at least because they fail to analyze the dose counters in existence prior to the priority date of the asserted patents." Anderson Rebuttal Rep. on Secondary Considerations ¶ 52; Anderson Opening Rep. ¶ 475 (similar).

115. I disagree with Mr. Anderson. These studies do support my opinion that Qvar® HFA with dose counter and ProAir® HFA with dose counter satisfied multiple, long-felt needs in the industry, including, for example, the need for a dose counter with superior functionality, accuracy (including with respect to under- and over-counting), reliability and/or robustness. *See, e.g.*, Given 2012[32] ("ProAir HFA [p]MDI with the new integrated dose counter functioned reliably and accurately in the clinical setting."); Chipps 2017[33] ("In patients with asthma and/or

[32] TEVADOC-00000010, at -10.

[33] TEVADOC-00000008, at -08.

COPD, albuterol inhalation aerosol (ProAir HFA) with dose counter, compared with the same product without dose counter, had significantly lower healthcare resource use including all-cause and respiratory-related inpatient [emergency department] visits, higher refill rates, and fewer exacerbations.").

116. The conclusions in Given 2012 and Chipps 2017 show that the dose counters used in Qvar® HFA with dose counter and ProAir® HFA with dose counter had superior functionality, accuracy (including with respect to under- and over-counting), reliability, and/or robustness. Further, as I explain in my Opening Report, based on the experience as treating physician in the field of pulmonary medicine, these were needs that had not been met by prior art devices or disclosures as of the priority date. Qvar® HFA with dose counter and ProAir® HFA with dose counter have received praise from physicians (including myself), patients, and regulators, including with respect to their superior functionality, accuracy (including, with respect to over- and under-counting), reliability, maintainability (and ability to be cleaned), robustness, manufacturability, minimal impact on device performance, and human factors (including aesthetics, ergonomics, and other human factors). *See* Panettieri Opening Rep. § VI.D (¶¶ 106-07).

c. Reliance on Ms. Carr's Testimony is Appropriate

117. [redacted]

118. [redacted]

[redacted]

119. [redacted]

[redacted]

120. As I set forth in my Opening Report, as of the priority date, there were multiple long-felt, unmet needs including a need for inhalers with dose counters that had sufficient functionality, accuracy (including with respect to under- and over-counting), reliability, maintainability (and ability to be cleaned), robustness, manufacturability, minimal impact on device performance, and human factors (including aesthetics, ergonomics, and other human factors). *See* Panettieri Opening Rep. § VI.A (¶¶ 45-82). Qvar® HFA with dose counter and ProAir® HFA with dose counter met these needs. *See* Panettieri Opening Rep. § VI.A.3 (¶¶ 83-96).

121. [redacted]

[redacted]

123. [redacted]

B. Failure of Others

124. According to Mr. Anderson, the "desirable features" that I identified in my Opening Report, "including compactness, ergonomics, maintainability, cleanability, ease of manufacture, ease of assembly, and expense lack any nexus to the claims of the Asserted

Patents." Anderson Rebuttal Rep. on Secondary Considerations ¶ 56; *see* Anderson Opening Rep. ¶ 477. I disagree.

125. As I set forth above, features such as ergonomics, maintainability, and cleanability have a nexus to the Asserted Claims. *See supra* §§ VI.A.1.b, VI.A.2.d, VI.A.3.a. Moreover, the other features that I identified in my Opening Report, including compactness, ease of manufacture, ease of assembly, and expense have a nexus to the Asserted Claims.

126. To begin with, I have been informed that nexus does not require that a claim expressly recite the advantages of a patented invention. As Dr. Lewis explains in his Reply Report, the combination of elements recited in the Asserted Claims sets forth an accurate and precise dose counter that is capable of fitting in a compact, hand-held inhalation device. *See* Lewis Reply Rep. § VI.A.2. Moreover, Dr. Lewis explains that the combination of elements recited in the Asserted Claims sets forth the spatial relationship of various features and components in the inhaler body, including support formations, the dose counter, actuation member, count pawl, etc. that allows devices that include the claimed inventions easier to manufacture and assemble. *See* Lewis Reply Rep. § VI.A.2. In offering his opinion, Mr. Anderson appears to focus on the fact that the Asserted Patents do not use the terms "compactness," "ease of manufacture," "ease of assembly," and "lack of expense" or other similar phrases. Mr. Anderson again misses the point. What is important here is that the inventions recited in the Asserted Claims provide the unique combination of elements from which these advantages flow. Unsurprisingly, the Asserted Claims do not refer to those terms expressly because they describe the inventions in terms of their design. In my opinion, however, it is those designs that solved the needs I described. Moreover, Devices that have superior

manufacturability and assembly lowers the costs of these devices, making them, in my opinion, more accessible and affordable to patients.

127. Additionally, Mr. Anderson states that "Teva's claims of secondary considerations are identical even though the claimed inventions [of] the four Asserted Patents are allegedly different, further showing that Teva has not demonstrated any nexus or connection between any actual Asserted Claim of an Asserted Patent and alleged secondary consideration." Anderson Opening Rep. ¶ 477. I disagree with Mr. Anderson. As explained above, these objective indicia of non-obviousness are attributable to the combination of elements recited in each of the Asserted Claims.

128. In addition, Mr. Anderson, citing to Section XI.A. of his Rebuttal Report, states that "others did not fail in making accurate, reliable, robust devices." Anderson Rebuttal Rep. on Secondary Considerations ¶ 57. Mr. Anderson is incorrect for the reasons I set forth above. *See supra* § VI.A.1.

129. Mr. Anderson also asserts that my opinion that the Newtec Dose Counting actuator "includes an imprecise counting mechanism is flawed" because "under Plaintiffs' construction, the claimed device encompasses such 'flawed' counting mechanisms." Anderson Rebuttal Rep. on Secondary Considerations ¶ 58.

130. Mr. Anderson is incorrect. Unlike Newtec's inhalation device, Qvar® HFA with dose counter and ProAir® HFA with dose counter include dose counters which provide patients with a precise count of doses remaining in the medicament canister. The Newtec inhalation device, on the other hand, provides patients with only a rough estimate of doses expended or remaining.

131. Moreover, as I explain above, Mr. Andersons's claim construction analysis is misplaced. The Asserted Claims require dose counters, and the devices that Mr. Anderson relies upon fall short of this requirement. I therefore disagree with him for the reasons stated above, and I incorporate that analysis as though fully set forth herein.

132. Finally, Mr. Anderson states that while I "criticize[d] devices by Aptar and Cohero that use electronic components," I "ignore[d] the plethora of non-electronic devices that were available, and successful, as of the filing of the Asserted Patents." Anderson Rebuttal Rep. on Secondary Considerations ¶ 59. Moreover, according to Mr. Anderson I failed to provide "any support" that "the electronic components have limited manufacturability, aesthetics, and/or ergonomic values, none of which have any nexus to the claims of the Asserted Patents." Anderson Rebuttal Rep. on Secondary Considerations ¶ 59; *see* Anderson Opening Rep. ¶ 477.

133. Mr. Anderson is incorrect. In my Opening Report, I set out several examples of devices—both electronic and non-electronic—that failed to achieve the desirable characteristics described above. *See* Panettieri Opening Rep. §§ VI.A-B. Moreover, and contrary to Mr. Anderson's assertion, I did provide support that the electronic components have limited

manufacturability, aesthetic, and/or ergonomic values. *See* Panettieri Opening Rep. § VI.A.2.c (¶¶ 75-82). Further, as I set out above, these desirable characteristics do have a nexus to the Asserted Claims. *See supra* § VI.A.1.b, VI.A.2.d, VI.A.3.a.

C. Industry Acceptance

134. Mr. Anderson asserts that my opinion that the nonobviousness of the Asserted Claims is evidenced by industry acceptance is "flawed." Anderson Rebuttal Rep. on Secondary Considerations ¶ 60; Anderson Opening Rep. ¶ 474 ("It is my understanding that [industry acceptance] is not evidence of non-obviousness"). I disagree.

135. To begin with, Mr. Anderson asserts that my opinion "appears to be conflated with alleged industry praise." Anderson Rebuttal Rep. on Secondary Considerations ¶ 60. I disagree with Mr. Anderson's characterization. It is not surprising that physicians, patients, and regulators in the industry who accepted Qvar® HFA with dose counter and ProAir® HFA with dose counter would also praise Qvar® HFA with dose counter and ProAir® HFA with dose counter. *See* Panettieri Opening Rep. ¶¶ 102-05.

136. Moreover, Mr. Anderson asserts that my reliance on the studies set out in Chipps 2017, Given 2012, and Kerwin 2017,[34] is misplaced because Teva funded those studies. *See* Anderson Rebuttal Rep. Objective Indica ¶ 60. However, as I discuss above, that Teva funded these studies does not undermine the robustness of their experimental design or their conclusions. *See supra* § VI.A.3.b. Moreover, it is common in the industry for companies to fund the studies of their particular devices. Physicians (such as myself) can evaluate such studies. I have done so here, and I believe that the results are convincing.

[34] TEVADOC-00000412.

137. In addition, Mr. Anderson asserts that I rely on these studies for the proposition that the "addition of a dose counter" alone is a secondary consideration of non-obviousness. *See* Anderson Rebuttal Rep. Objective Indica ¶ 60. I disagree with Mr. Anderson. As I set forth in my Opening Report, the findings in these studies show that patients praise these medications and inhalation devices, including with respect to their superior functionality, accuracy (including, with respect to over- and under-counting), reliability, maintainability (and ability to be cleaned), robustness, manufacturability, minimal impact on device performance, and human factors (including aesthetics, ergonomics, and other human factors). *See* Panettieri Opening Rep. ¶ 105; Given 2012 ("ProAir HFA [p]MDI with the new integrated dose counter functioned reliably and accurately in the clinical setting."); Chipps 2017[35] ("In patients with asthma and/or COPD, albuterol inhalation aerosol (ProAir HFA) with dose counter, compared with the same product without dose counter, had significantly lower healthcare resource use including all-cause and respiratory-related inpatient [emergency department] visits, higher refill rates, and fewer exacerbations."); Kerwin 2017[36] ("In a real-world setting, asthma patients using ProAir HFA with [dose counter] experienced significantly fewer hospitalizations and [emergency department] visits compared with patients using ProAir HFA without [dose counter.]"). This is all consistent with my experience as a treating physician.

138. [redacted]

[35] TEVADOC-00000008, at -08.

[36] TEVADOC-00000412.

[redacted]

139. Moreover, Mr. Anderson states that in my view, "any inhaler with a dose counter that receives FDA approval (which comprises most inhalers sold in the U.S. in the last 15 years) is accepted by the industry. FDA approval of Qvar and ProAir does not evidence that non-obviousness of the alleged inventions of the asserted patents." Anderson Rebuttal Rep. Objective Indica ¶ 61; Anderson Opening Rep. ¶ 474 ("The FDA has approved numerous dose counters."). I disagree with Mr. Anderson's characterization of my opinion and with his conclusion. I did not opine that FDA approval alone of Qvar® HFA with dose counter and ProAir® HFA with dose counter evidenced industry acceptance. *See* Panettieri Opening Rep. ¶¶ 102-05. As I explain in my Opening Report, dose counters comprising the claimed combinations of components, configurations, and attachments have received acceptance by regulators *as well as* physicians and patients. *See* Panettieri Opening Rep. ¶¶ 102-05. Notably, nowhere in his report does Mr. Anderson provide any evidence that physicians, patients, or regulators in the industry rejected Qvar® HFA with dose counter or ProAir® HFA with dose

counter or found that Qvar® HFA with dose counter or ProAir® HFA with dose counter did not have the claimed properties of the Asserted Claims.

D. Praise

140. Mr. Anderson states that industry praise that Qvar® HFA with dose counter and ProAir® HFA with dose counter that I rely on in my Opening Report does not evidence non-obviousness. *See* Anderson Opening Rep. ¶ 62. I disagree with Mr. Anderson.

141. First, Mr. Anderson asserts that my reliance on the studies set out in Chipps 2017, Given 2012, and Kerwin 2017, is misplaced because Teva funded those studies. *See* Anderson Rebuttal Rep. Objective Indica ¶ 62. However, as I discuss above, that Teva funded these studies does not undermine the robustness of their experimental design or their conclusions. *See supra* § VI.A.3.b.

142. [redacted]

143. All of this is consistent with the praise Qvar® HFA with dose counter and ProAir® HFA with dose counter has received from physicians, patients, and regulators. Notably, Mr. Anderson provides no contrary evidence.

E. Copying

144. Mr. Anderson asserts that my opinion that the nonobviousness of the Asserted Claims is evidenced by Cipla's and Aurobindo's copying the claimed inventions in the Asserted

Patents is flawed. *See* Anderson Rebuttal Rep. on Secondary Considerations ¶ 63; Anderson Opening Rep. ¶ 476. I disagree with Mr. Anderson.

145. To begin with, Mr. Anderson suggests that I failed to provide any support for my opinion. *See* Anderson Rebuttal Rep. on Secondary Considerations ¶ 63 ("He provides no cited documents or testimony to support his opinion."). While I did not offer an independent opinion on this issue, here and in my Opening Report, I reference Dr. Lewis's Opening Reports, in which he explains that Aurobindo and Cipla infringe the Asserted Claims. *See* Panettieri Opening Rep. ¶ 108.

146. Moreover, Mr. Anderson asserts my "opinion is somewhat inexplicable given that Cipla's ANDA Product utilizes the device describes in the prior art '406 Publication." Anderson Rebuttal Rep. on Secondary Considerations ¶ 63; Anderson Opening Rep. ¶ 476 ("I understand that Defendants use a dose counter disclosed in the '406 Publication, which predates the Asserted Patents."). While I did not offer an independent opinion on this issue, I reference Dr. Lewis's Responsive Report, in which Dr. Lewis explains that the dose counter disclosed in the '406 Publication is not the same dose counter that is used in Cipla's and Aurobindo's ANDA Products. *See* Lewis Rebuttal Rep. §§ IV.A, VI.

147. In addition, Mr. Anderson asserts that the testimony of Mr. Walsh confirms that Cipla and Aurobindo did not copy the claimed inventions in the Asserted Patents. *See* Anderson Rebuttal Rep. on Secondary Considerations ¶ 63. Mr. Anderson's assertion is incorrect. Mr. Walsh is not trained to render legal conclusions on issues relating to patent infringement. That he testified that he has not "come across a dose counter that's a copy of the one Teva uses" does not mean that Aurobindo's and Cipla's ANDA Products do not infringe the Asserted Claims.

Indeed, Dr. Lewis's Opening Reports make clear that Aurobindo's and Cipla's ANDA Products do infringe the Asserted Claims. *See generally* Lewis Opening Reps. § VIII.

148. Finally, Mr. Anderson states that "rel[ying] on the filing of Defendants' ANDAs as evidence of copying . . . is not compelling evidence of nonobviousness." Anderson Rebuttal Rep. on Secondary Considerations ¶ 64 (citing cases). Nowhere in my report did I make that assertion. Instead, I stated that "Aurobindo and Cipla chose to copy the Asserted Claims by seeking approval from FDA to market generic versions of Qvar®, which is an embodiment of the claimed inventions. *As set forth in Dr. Lewis's Opening Reports, Aurobindo and Cipla infringe the Asserted Claims*." Panettieri Opening Rep. ¶ 108 (emphasis added).

Dated: July 12, 2022 By: */s/* Reynold A. Panettieri, Jr.